EX

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,209	10/09/2001	Winston Z. Ho		5806

26588 7590 07/26/2005

LIU & LIU
444 S. FLOWER STREET SUITE 1750
LOS ANGELES, CA 90071

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,209	HO, WINSTON Z.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 21-30* is/are pending in the application.

4a) Of the above claim(s) *23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action filed 27 June 2005 is persuasive and, therefore, the finality of that action is withdrawn.

Election/Restrictions

2. Applicant argues claims 23-26 require a reaction zone, however the method of group I also requires terminating flow, which is not required of the method of group II. Because the groups require different elements, a separate search would be required to search groups I and II. Furthermore, since the methods of groups I and II are patentably distinct methods, the restriction of claims 27-30 is proper. Claims 27-30 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawn Rejections

3. Previous rejection of claim 1 under 35 USC 112, first paragraph has been withdrawn. Rejections of claims 1-11 under 35 USC 112, second paragraph have been withdrawn.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-11, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification fails to describe terminating flow to allow a portion of the fluid to react with the at least one biological probe.

5. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the fluid is meant to flow "pass and beyond" the reaction zone. It is unclear whether the fluid and the sample is meant to flow beyond the reaction zone or whether the sample is meant to bind to the biological probes within reaction zone while the fluid continues to flow through the reaction zone. Furthermore, if the flow is terminated in order to allow a portion of the fluid to react with the biological probes, it is unclear if by transporting the fluid passed the reaction zone allows for reaction between the flowing fluid and the reaction zone.

Claim Rejections - 35 USC § 102

1. Claims 1, 3-11, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Blackburn (US 2003/0190608).

Blackburn teaches a method for performing biological reaction in a microfluidic biochip platform, comprising the steps of: providing a plurality of microfluidic channels (Fig. 7C; par. 0049), said microfluidic channels each including a reaction zone defined by a section of a curved serpent-like structure (32, upper left hand corner, 34, Fig. 6; par. 0053, 0155), the reaction zone having a constant cross section area (32, Fig. 6; par. 0164); immobilizing at least one biological probe in the reaction zone (par. 0049, 0152), to define a constant and consistent reaction volume independent of physical flow barriers (par. 0373) in the microchannels to allow fluid to pass the reaction zone (reaction volumes are the same size through the biochannel, and are therefore constant, consistent, and independent of physical flow barriers, the reaction volumes also allow fluid to pass the reaction zone; par. 0150); and transporting fluid in the microfluidic channels to

the reaction zone (par. 0156) and terminating flow (par. 0335; 372). Blackburn fails to specifically teach terminating flow to allow a portion of the fluid to react with the at least one biological probe. However, Blackburn teaches terminating flow and altering flow to promote binding (lower right hand corner, 34, Fig. 6; par. 0154, 0156). The method taught by Blackburn is further capable of creating a reaction volume is a product of the cross-section area multiplied with the length of the microfluidic channels, because claim 1 does not recite any further product or method limitations in order to determine a reaction volume being a product of the cross section multiplied by the length.

Regarding claims 3-5, Blackburn teaches a the microfluidic biochip further comprising microfluidic channels having cross sectional dimensions on the order of 0.1 μm to 500 μm (par. 0164), which encompasses the recited range of between 0.5 μm and 2mm. Blackburn further teaches at least one sample well containing a sample (chamber, Fig. 7A, B; par. 0059, 0099, 0167) and at least one reagent well containing a reagent (device can further comprise wells for samples and reagents; par. 0099), wherein a portion of the microfluidic channels is connected to the at least one sample well and the at least one reagent well (microchannels are placed between wells for samples and reagents; par. 0099). Blackburn also teaches fluid in the microfluidic channels transported by a pressuring mechanism that provides a forward-moving fluid (par. 0156).

With respect to claim 6, Blackburn teaches at least one biological probe immobilized on magnetic beans (par. 0266), and wherein the step of immobilizing at least one probe in the reaction zone comprises: transporting the magnetic beads through microfluidic channels (fluid flow control system allows fluid to pass over DNA separation chamber, therefore the magnetic

beads are transported through microfluidic channels, par. 0337); providing at least one external magnet adjacent a reaction zone (electromagnet, par. 0339, 0357); and activating at least one external magnet to trap the magnetic beads (par. 0337, 0339, 0357).

Regarding claim 7, Blackburn teaches the method comprising: at least one biological probe immobilized on a first surface of a first plate (biological molecules are adhered to surfaces, which can be interpreted as a "first plate" and coupled with the microfluidic channel in the second plate; par. 0159, 0160, 0163); a microfluidic channel patterned on a second surface of a second plate (microchannels can be etched within one plane of two or more planar substrates stacked together; par. 0151); and the first surface of the first plate coupled with the second surface of the second plate (two or more planar substrates are stacked and joined together; par. 0145, 0151).

With respect to claims 8-11, Blackburn teaches the probe being a protein (par. 0103), nucleic acid (par. 0104), or biological cell (par. 0103). Blackburn further teaches the method comprising the step of detecting a reaction in the reaction zone (target analytes bind in reaction zone and are detected; par. 0102).

Regarding claims 21 and 22, Blackburn teach transporting fluid passed and beyond the reaction zone (fluid passes DNA separation chamber, which can be a reaction zone; par. 0053, 0163, 0337), and although Blackburn does not specifically teach a reaction volume, a volume of fluid remains in the reaction zone, and can be referred to as a reaction volume. Blackburn further teach transporting fluid from the reaction zone after a reaction has taken place, by flowing fluid passed the reaction zone in the same direction as flow of fluid into the reaction

zone prior to the reaction taking place (fluid is flowed through the reaction zone and realized from the reaction zone after binding takes place; par. 0337).

Response to Arguments

2. Applicant's arguments, see pages 10-12, filed 27 June 2005, with respect to rejection of claim 1 under 35 USC 112, first paragraph and rejection of claims 1 and 3-11 under 35 USC 112, second paragraph have been fully considered and are persuasive. The rejections of claims 1 and 3-11 under 35 USC 112, first paragraph and 112, second paragraph have been withdrawn.

3. Applicant's arguments regarding rejection of claims 21 and 22 under 35 USC 112, second paragraph have been fully considered but they are not persuasive. Claim 1 recites terminating flow in order to promote binding in the reaction zone, while claims 21 and 22 recites transporting flow to pass and beyond the reaction zone. Therefore it is still not clear whether the fluid is intended to flow beyond the reaction zone or terminate flow in the reaction zone.

4. Applicant's arguments regarding rejection of claims 1, 3-11 and 21-22 under 35 USC 102(e) filed 27 June 2005 have been fully considered but they are not persuasive. Applicant argues Blackburn fails to disclose a serpent-like flow structure that defines a constant and consistent reaction volume independent of physical flow barriers. However, Blackburn teaches a serpent-like structure (Fig. 1) and a constant and consistent reaction volume (Fig. 4, the cross-section and length of the channel remain constant and consistent, therefore the reaction volume remains constant and consistent) independent of physical flow barriers in the microfluidic channel (no physical flow barriers are present in the reaction zone or interfere with a constant and consistent reaction volume). The rejected claims do not recite termination of flow

independent of physical flow barriers, and therefore flow can be terminated by a valve or hydrophobic material in the microfluidic channel as discussed above.

5. Blackburn does not disclose a continuous flow system, and in fact teaches the termination of flow at paragraphs 272-273. Blackburn also teaches alteration of flow in order to allow a portion of fluid to react with biological probes at paragraphs 154-156. Therefore, the method of terminating flow as taught by Blackburn would be capable of altering flow by terminating flow to allow a portion of the fluid to react with the at least one biological probe.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
07/22/05